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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/897,455 07/22/97 STACHE

U 2481.1403-02

EXAMINER

HM12/0717

BADIO, B

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Applicant(s)

08/897,455

Applicant(s)

STACHE ET AL.

Examiner

Barbara P Badio, Ph.D.

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1616

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 11-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

First Office Action on the Merits

Continued Prosecution Application

1. The request filed on May 31, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/897,455 is acceptable and a CPA has been established. An action on the CPA follows.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

3. Claims 11-22 are pending in the present application. Claims 18-22 drawn to a method of making stand withdrawn from further consideration as being drawn to a non-elected invention (see restriction requirement made in Paper No. 14). Claims 11-17 stand rejected as indicated below.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1, 4-5 and 7-10 under 35 USC 103(a) over Page et al. ('971) is made moot by the cancellation of the instant claims.
5. Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. ('971).

Page et al. generically teach 17,21-dicarboxylic acid esters of 4-pregnen-3,20-dione having either an oxo, halogen or a hydroxyl group in the 11-position and substituents in the 6, 9 and 16 positions which include those recited by the claimed invention. The reference teaches the compounds may also contain a double bond in the 1-position (col. 1, lines 1-55; col. 8, lines 47-59) and the use of the compounds in the treatment of corticosteroid-responsive dermatosis (col. 8, lines 30-41).

The instant claims differ from the reference by reciting specific species not exemplified by the reference, i.e., compounds wherein R(1) is phenyl which may be substituted as indicated by the claimed invention. However, the generic disclosure of Page suggests most of the substituents of the claimed "Markush" structure including the claimed aralkyl ester group attached to the 21-position. Page discloses compounds of formula (I) wherein R₅ is OC(O)-R", wherein R" is an alkyl group of 1 to 16 carbon atoms, a phenyl group or an aralkyl group of 7 to 8 carbon atoms (i.e., -(CH₂)₁₋₂-phenyl). Applicant's claimed compound defining R(1) as a phenyl group is thus within the scope of the disclosure of Page et al. The motivation to make the claimed compounds is based on the desire to make additional compounds useful in the treatment of corticosteroid-responsive dermatosis as taught by the prior art.

6. Claims 11, 12, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Djerassi et al. ('429).

Djerassi et al. teach a generic group of 17,21-diesters of 6 α ,16 α -dimethyl-4-pregnen-17 α ,21-diol-3,20-diones (see the entire article, especially col. 1, lines 14-53).

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The reference teaches acyl groups such as acetyl and phenylpropionyl (col. 1, lines 44-54), the optional double bond in the 1-position and that the compounds exhibit anti-inflammatory and glycogenic activity (col. 1, lines 19-26).

The instant claims differ from the reference by reciting specific species not exemplified by the reference, i.e., compounds wherein R(1) is phenyl which may be substituted as indicated by the claimed invention. However, Djerassi teach a variety of specific acyl groups including phenylpropionyl attached to the 21-position. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the present application to select any of the species of the genus taught by the reference, including those of the instant claims, because he would have the reasonable expectation that any of the species of the genus would have similar properties, and, thus, the same use as the genus as a whole. The motivation to make the claimed compounds is based on the desire to make additional compounds useful as taught by the prior art.

7. Claims 11, 12 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowers ('391).

Bowers teaches a generic group of $6\alpha,9\alpha,11\beta$ -trichloro and 6α -fluoro- $9\alpha,11\beta$ -dichloro pregnenes (see the entire article, especially col. 1, lines 14-71). The reference teaches acyl groups such as acetyl and phenylpropionyl (col. 1, lines 62-65), the optional double bond in the 1-position and that the compounds exhibit anti-estrogenic, anti-inflammatory and glycogenic activity and are useful in alleviation of inflammatory conditions (col. 1, lines 66-71).

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The instant claims differ from the reference by reciting specific species not exemplified by the reference, i.e., compounds wherein R(1) is phenyl which may be substituted as indicated by the claimed invention. However, Bowers teaches a variety of specific acyl groups including phenylpropionyl attached to the 21-position. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the present application to select any of the species of the genus taught by the reference, including those of the instant claims, because he would have the reasonable expectation that any of the species of the genus would have similar properties, and, thus, the same use as the genus as a whole. The motivation to make the claimed compounds is based on the desire to make additional compounds useful as taught by the prior art.

8. Claims 11, 12, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oughton et al. ('940).

Oughton et al. teach a generic group of 1,4-diene-3-keto steroid compounds having therapeutic activity (see the entire article, especially col. 1, lines 11-24; col. 2, lines 10-29). The reference teaches acyl groups such as acetyl and phenylacetyl (col. 2, lines 24-26).

The instant claims differ from the reference by reciting specific species not exemplified by the reference, i.e., compounds wherein R(1) is phenyl which may be substituted as indicated by the claimed invention. However, Oughton teaches a variety of specific acyl groups including phenylacetyl attached to the 21-position. Therefore, it

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would have been obvious to one having ordinary skill in the art at the time of the present application to select any of the species of the genus taught by the reference, including those of the instant claims, because he would have the reasonable expectation that any of the species of the genus would have similar properties, and, thus, the same use as the genus as a whole. The motivation to make the claimed compounds is based on the desire to make additional compounds useful as taught by the prior art.

Other Matters

9. The structure of formula I in claim 11 is incorrect. It is noted that -O-CO-R(2) is in the β position and not the α position as originally claimed and disclosed by the present specification. Correction is required.

10. Applicant's argument against Page et al. is noted. The argument is based mainly on the fact that the reference does not exemplify a compound wherein R(1) is phenyl or substituted phenyl as presently claimed. As stated in the previous Office Action and the examiner's answer, the reference has to be evaluated for what it teaches one having ordinary skill in the art and not on the exemplified compounds shown in the prior art. Based on the teachings of the prior art, the claimed compounds are prima facie obvious.

The reference exemplifies more than 10 compounds that differ from the claimed compound by one substituent. The reference also teaches an equivalence between the exemplified groups and the presently claimed group attached to the 21-position of the

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steroid moiety. Therefore, modification of the exemplified compounds would result in only one change and not the various selections as discussed by applicant.

Applicant argues that one skilled in the art would not have been motivated to modify examples 9 and 19 of Page because the compounds have poor stability. Examples 9 and 19 are just two of the exemplified compounds. Reference can also be made to examples 3-5, 10, 13-15, 19-20 and 22-24. Even if examples 9 and 19 were the only compounds exemplified by Page, the new evidence as presented by applicant does not alter the obviousness of the claimed compound. The issue is not whether the compounds are stable or not. The issue is whether based on the prior art, the claimed compounds would have been obvious to the skilled artisan in the art. The fact remains that Page teaches an equivalence between various groups in that position and one of the groups is that of the claimed invention.

Applicant also argues that the claimed compounds have unexpected superior properties. The present specification does not compare the closest prior art compound to those of the claimed invention. Therefore, applicant's evidence of unexpected superior properties does not overcome the rejection made over Page et al.

Applicant also has made reference to a number of patents as a showing that the prior art as a whole do not made obvious the claimed invention. The examiner notes the additional references cited above.

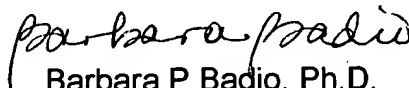
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Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
July 13, 2001